[Federal Register: January 30, 1996 (Volume 61, Number 20)]
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DEPARTMENT OF TRANSPORTATION
National Highway Traffic Safety Administration
[NHTSA Docket No. 94-021; Notice 3]

Highway Safety Programs; Model Specifications for Devices To Measure Breath Alcohol

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice.

SUMMARY: This notice amends the Conforming Products List for instruments that conform to the Model Specifications for Evidential Breath Testing Devices (58 FR 48705).

EFFECTIVE DATE: January 30, 1996.

FOR FURTHER INFORMATION CONTACT: Dr. James F. Frank, Office of Alcohol and State Programs, NTS-21, National Highway Traffic Safety Administration, 400 Seventh Street, S.W., Washington, D.C. 20590; Telephone: (202) 366-5593.

SUPPLEMENTAL INFORMATION: On November 5, 1973, the National Highway Traffic Safety Administration (NHTSA) published the Standards for Devices to Measure Breath Alcohol (38 FR 30459). A Qualified Products List of Evidential Breath Measurement Devices comprised of instruments that met this standard was first issued on November 21, 1974 (39 FR 41399).

On December 14, 1984 (49 FR 48854), NHTSA converted this standard to Model Specifications for Evidential Breath Testing Devices, and published a Conforming Products List (CPL) of instruments that were found to conform to the Model Specifications as Appendix D to that notice (49 FR 48864).

On September 17, 1993, NHTSA published a notice (58 FR 48705) to

amend the Model Specifications. The notice changed the alcohol concentration levels at which instruments are evaluated, from 0.000, 0.050, 0.101, and 0.151 BAC, to 0.000, 0.020, 0.040, 0.080, and 0.160 BAC; added a test for the presence of acetone; and expanded the definition of alcohol to include other low molecular weight alcohols including methyl or isopropyl. On March 16, 1995, the most recent amendment to the Conforming Products List (CPL) was published (60 FR 14320), identifying those instruments found to conform with the Model Specifications.

Since the last publication of the CPL, three (3) instruments have been evaluated and found to meet the model specifications, as amended on September 17, 1993, for mobile and non-mobile use. They are: CMI, Inc.'s ``Intoxilyzer 300'' (which is the same as Lion Laboratories' ``Alcolmeter 300'' that will also be listed); National Patent Analytical Systems, Inc.'s ``BAC Verifier Datamaster'' (which is the same as Verax Systems' ``BAC Verifier Datamaster'' that will also be listed); and National Draeger's ``Alcotest 7110 MKIII''. Additionally, four devices currently listed under the CMI brand name (Intoxilyzer 200, Intoxilyzer 200D, Intoxilyzer 1400 and Intoxilyzer 5000 CD/FG5) will also be listed under the Lion Laboratories brand name. Lion Laboratories and CMI, Inc. are both wholely-owned subsidiaries of the same parent company (MPD, Inc.) and the devices are the same whether they are sold by CMI or Lion Laboratories.

In accordance with the foregoing, the CPL is therefore amended, as set forth below.

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Conforming Products List of Evidential Breath Measurement Devices

Manufacturer and model	Mobile	Nonmobile
Alcohol Countermeasures System, Inc., Port Huron, MI:		
Alert J3AD*	X	X
BAC Systems, Inc., Ontario, Canada:		
Breath Analysis Computer*	X	
CAMEC Ltd., North Shields, Tyne and Ware, England:		
IR Breath Analyzer*	X	X
CMI, Inc., Owensboro, KY:		
Intoxilyzer Model:		
200	X	X
200D	X	X
300	X	X
400	X	X
1400	X	X
4011*	X	X
4011A*	X	X

4011AS*	X	X
4011AS-A*	X	X
4011AS-AQ*	X	X
4011 AW*	X	X
4011A27-10100*	X	X
4011A27-10100 with filter*	X	X
5000	X	X
5000 (w/Cal. Vapor Re-Circ.)	X	X
5000 (w/3/8'' ID Hose option)	X	X
5000CD	X	X
5000CD/FG5	X	X
5000 (CAL DOJ)	X	X
5000VA	X	X
PAC 1200*	X	X
S-D2	X	X
Decator Electronics, Decator, IL:		
Alco-Tector model 500*		X
Gall's Inc., Lexington, KY:		
Alcohol Detection System-A.D.S. 500	X	X
Intoximeters, Inc., St. Louis, MO:		
Photo Electric Intoximeter*		X
GC Intoximeter MK II*	X	X
GC Intoximeter MK IV*	X	X
Auto Intoximeter*	X	X
Intoximeter Model:		
3000*	X	X
3000 (rev B1)*	X	X
3000 (rev B2)*	X	X
3000 (rev B2A)*	X	X
3000 (rev B2A) w/FM option*	X	X
3000 (Fuel Cell)*	X	X
3000 D*	X	X
3000 DFC*	X	X
Alcomonitor		X
Alcomonitor CC	X	X
Alco-Sensor III	X	X
Alco-Sensor IV	X	X
RBT III	X	X
RBT III-A	X	X
RBT IV	X	X
Intox EC-IR	X	X
Portable Intox EC-IR	X	X
Komyo Kitagawa, Kogyo, K.K.:		
Alcolyzer DPA-2*	X	X
Breath Alcohol Meter PAM 101B*	X	X
Life-Loc, Inc., Wheat Ridge, CO:		
PBA 3000B	X	X
PBA 3000-P*	X	X
Lion Laboratories, Ltd., Cardiff, Wales, UK:		
Alcolmeter Model:		
300	X	X
400	X	X
AE-D1*	X	X
SD-2*	X	X
EBA*	X	X
Auto-Alcolmeter*		X
Intoxilyzer Model:		
200	X	X

200D	X	X
1400	X	X
5000 CD/FG5	X	X
Luckey Laboratories, San Bernadino, CA:		
Alco-Analyzer Model:		
1000*		X
2000*		X
National Draeger, Inc., Durango, CO:		
Alcotest Model:		
7010*	X	X
7110*	X	X
7110 MKIII	X	X
7410	X	X
Breathalyzer Model:		
900*	X	X
900A*	X	X
900BG*	X	X
7410	X	X
7410-II	X	X
National Patent Analytical Systems, Inc., Mansfield, OH:		
BAC DataMaster	X	X
BAC Verifier Datamaster	X	X
Omicron Systems, Palo Alto, CA:		
Intoxilyzer Model:		
4011*	X	X
4011AW*	X	X
Plus 4 Engineering, Minturn, CO:		
5000 Plus4*	X	X
Siemans-Allis, Cherry Hill, NJ:		
Alcomat*	X	X
Alcomat F*	X	X
Smith and Wesson Electronics, Springfield, MA:		
Breathalyzer Model:		
900*	X	X
900A*	X	X
1000*	X	X
2000*	X	X
2000 (non-Humidity Sensor)*	X	X
Sound-Off, Inc., Hudsonville, MI:		
AlcoData	X	X
Stephenson Corp.:		
Breathalyzer 900*	X	X
U.S. Alcohol Testing, Inc./Protection Devices, Inc., Rancho Cucamonga, CA:		
Alco-Analyzer 1000		X
Alco-Analyzer 2000		X
Alco-Analyzer 2100	X	X
Verax Systems, Inc., Fairport, NY:		
BAC Verifier*	X	X
BAC Verifier Datamaster	X	X
BAC Verifier Datamaster II*	X	X

*Instruments marked with an asterisk (*) meet the Model Specifications detailed in 49 FR 48854 (December 14, 1984) (i.e., instruments tested at 0.000, 0.050, 0.101, and 0.151 BAC.) Instruments not marked with an asterisk meet the Model Specifications detailed in 58 FR 48705 (September 17, 1993), and were tested at BACs=0.000, 0.020, 0.040,

0.080, and 0.160.

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(23 U.S.C. 402; delegations of authority at 49 CFR 1.50 and 501.1)

Issued on: January 24, 1996.

James Hedlund,

Associate Administrator for Traffic Safety Programs.

[FR Doc. 96-1734 Filed 1-29-96; 8:45 am]
BILLING CODE 4910-59-P

[Federal Register: August 15, 1995 (Volume 60, Number 157)]
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From the Federal Register Online via GPO Access [wais.access.gpo.gov]

DEPARTMENT OF TRANSPORTATION
National Highway Traffic Safety Administration
[NHTSA Docket No. 94-004; Notice 4]

Highway Safety Programs; Conforming Products List of Screening Devices to Measure Alcohol in Bodily Fluids

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Ntoice.

SUMMARY: This notice amends the Conforming Products List (CPL) of devices that conform to the Model

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Specifications for Screening Devices that measure alcohol in bodily fluids (59 FR 39382).

EFFECTIVE DATE: August 15, 1995.

FOR FURTHER INFORMATION CONTACT:
Dr. James F. Frank, Office of Alcohol and State Programs, NTS-21, National Highway Traffic Safety Administration, 400 Seventh St., SW., Washington, DC 20590; Telephone: (202) 366-9581.

SUPPLEMENTARY INFORMATION: On August 2, 1994, Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids were published in the Federal Register (59 FR 39382). In these model specifications, NHTSA recognized industry efforts to develop new technologies. These specifications establish performance criteria and methods for testing alcohol screening devices using either breath or other bodily fluids to measure alcohol content. NHTSA established these specifications to support State laws that target youthful offenders (i.e., ``zero tolerance'' laws) and the Department of Transportation's initiative to

prevent alcohol misuse. NHTSA published its first CPL for screening devices on December 2, 1994 (59 FR 61923; with a correction in 59 FR 65128). Five devices were on that first list.

Since the publication of that list, two additional disposable, single-use saliva-alcohol screening devices have been evaluated at the Volpe National Transportation System Center in Cambridge, MA and found to conform to the model specifications for screening devices: Chematics' ``Alco-Screen 02<SUP>TM" and Roche Diagnostic Systems' ``On-Site Alcohol".

It should be noted, however, that while the ALCO-SCREEN 02<SUP>TM saliva-alcohol screening device manufactured by Chematics, Inc. passed the requirements of the model specifications when tested at 40 deg.C (104 deg.F), the manufacturer has indicated that the device cannot exceed storage temperatures of 27 deg.C (80 deg.F). (Instructions to this effect are stated on all packaging accompanying the device.) Accordingly, the device should not be stored at temperatures above 27 deg.C (80 deg.F) and, if the device is stored at or below 27 deg.C (80 deg.F) and used at higher temperatures, the test should be completed immediately. When these devices were stored at or below 27 deg.C (80 deg.F) and tested at 40 deg.C (104 deg.F) immediately (i.e., within a minute), the devices met the model specifications and the results persisted for 10-15 minutes. When these devices were stored at or below 27 deg.C (80 deg.F) and were equilibrated at 40 deg.C (104 deg.F) for an hour prior to sample application, the devices failed to meet the model specifications. Storage at temperatures above 27 deg.C (80 deg.F), for even brief periods of time, may result in false negative readings.

It should be noted also that while the ON-SITE ALCOHOL saliva-alcohol screening device manufactured by Roche Diagnostics Systems passed all of the requirements of the model specifications, readings should be taken only after the time specified by the manufacturer. For valid readings, the user should follow the manufacturer's instructions. Readings should be taken one (1) minute after a sample is introduced at or above 30 deg.C (86 deg.F); readings should be taken after two (2) minutes at 18-29 deg.C (64 deg.F-84 deg.F); and readings should be taken after five (5) minutes when the sample is introduced at temperatures at or below 17 deg.C (63 deg.F). If the reading is taken before five minutes have elapsed under the cold conditions, the user is likely to obtain a reading that underestimates the actual saliva-alcohol level.

The Conforming Products List is therefore amended as follows:

Conforming Products List of Alcohol Screening Devices

Manufacturer	Devices(s)

(1) Alco Check International* Hudsonville, MI.....	Alco Check 3000 D.O.T. Alco Screen 3000.
(2) Chematics, Inc., North Webster, IN.....	ALCO-SCREEN 02<SUP>TM.\1\
(3) Guth Laboratories, Inc.*, Harrisburg, PA.....	Alco Tector Mark X. Mark X Alcohol Checker.
(4) Repco Marketing, Inc., Raleigh, NC.....	Alco Tec III.
(5) Roche Diagnostic Systems, Branchburg, NJ.....	On-Site Alcohol.\2\
(6) Sound Off, Inc.,* Hudsonville, MI.....	Digitox D.O.T. Alco Screen 1000.
(7) STC Diagnostics, Inc., Bethlehem, PA.....	Q.E.D. A150 Saliva Alcohol Test.

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* The devices listed by this manufacturer are the same device sold under two different names.

\1\ It should be noted, however, that while the ALCO-SCREEN 02<SUP>TM saliva-alcohol screening device manufactured by Chematics, Inc. passed the requirements of the model specifications when tested at 40 deg. C (104 deg. F), the manufacturer has indicated that the device cannot exceed storage temperatures of 27 deg. C (80 deg. F). (Instructions to this effect are stated on all packaging accompanying the device.) Accordingly, the device should not be stored at temperatures above 27 deg. C (80 deg. F) and, if the device is stored at or below 27 deg. C (80 deg. F) and used at higher temperatures, the test should be completed immediately. When these devices were stored at or below 27 deg. C (80 deg. F) and tested at 40 deg. C (104 deg. F) immediately (i.e., within a minute), the devices met the model specifications and the results persisted for 10-15 minutes. When these devices were stored at or below 27 deg. C (80 deg. F) and were equilibrated at 40 deg. C (104 deg. F) for an hour prior to sample application, the devices failed to meet the model specifications. Storage at temperatures above 27 deg. C (80 deg. F), for even brief periods of time, may result in false negative readings.

\2\ While this device passed all of the requirements of the model specifications, readings should be taken only after the time specified by the manufacturer. For valid readings, the user should follow the manufacturer's instructions. Readings should be taken one (1) minute after a sample is introduced at or above 30 deg. C (86 deg. F); readings should be taken after two (2) minutes at 18 deg. C-29 deg. C (64.4 deg. F-84.2 deg. F); and readings should be taken after five (5) minutes when testing at temperatures at or below 17 deg. C (62.6 deg. F). If the reading is taken before five (5) minutes has elapsed under the cold conditions, the user is likely to obtain a reading that underestimates the actual saliva-alcohol level.

Note that devices 1, 3, 4 and 6 are breath alcohol testers that use semiconductor type sensors. Devices 2, 5, and 7 are saliva alcohol testers that use enzymatic techniques to measure the alcohol concentration in a saliva sample.

Issued on: August 10, 1995.

James Hudlund,

Acting Associate Administrator for Traffic Safety Programs.

[FR Doc. 95-20179 Filed 8-14-95; 8:45 am]
BILLING CODE 4910-59-M